REMARKS

Claims 1-7 and 9-11 are pending after this amendment. Claim 8 has been canceled. Claim 1 has been amended to recite that the chronic spinal mechanical pain is relieved for at least three months following the most recent administration of the bisphosphonate, and the bisphosphonate is pamidronate or zoledronic acid. Support for these amendments can be found in the specification at, for example, p. 7, ll. 12-14 and p. 9, ll. 1-2; and original claims 9 and 10.

I. The rejection of claims 1-8 and 11 under 35 U.S.C. § 112, first paragraph, enablement

Claims 1-8 and 11 have been rejected because the Examiner contends that, although the specification is enabling for treating chronic spinal mechanical pain by administering pamidronate or zoledronic acid, the specification does not enable all bisphosphonates. Office Action, p. 2.

Claim 1, the only independent claim, has been amended to recite that the bisphosphonate is pamidronate or zoledronic acid. Thus, this rejection should be withdrawn because the specification is enabling for these specific bisphosphonates. *See* Office Action, p. 2.

II. The rejection of claims 1-9 and 11 under 35 U.S.C. § 103(a) as obvious over Geusens et al., J of Clin Densitometry, 2001;4:389-394

The Examiner has maintained the rejection of claims 1-9 and 11 as obvious over Geusens et al., J of Clin Densitometry, 2001;4:389-394 ("Geusens"). According to the Examiner, Geusens discloses the case history of an 18-year old boy treated with intravenous pamidronate (a bisphosphonate) for extreme back pain resulting from multiple vertebral fractures. The pamidronate was administered intermittently over a nine month period. The patient's back pain progressively improved. Office Action, page 6.

The Examiner acknowledges that Geusens does not teach treating chronic spinal mechanical pain, i.e., any back pain lasting more than twelve weeks which is not caused by cancer or an osteoporotic compression fracture, and the treatment comprising providing prolonged pain relief. Office Action, p. 6-7. However, the Examiner contends that it would have been obvious to use pamidronate for the treatment of any back pain because Geusens discloses the effectiveness of pamidronate in pain management. *Id.* at 7. The Examiner further contends that the prolonged pain

relief limitation would have been obvious because Geusens "teach that intermittent IV infusions of pamidronate were given at dose of 30 mg infusion, 300 mg in total over 9 month. Geusens et al.'s duration of therapy over 9 month comprising administration of pamidronate obviously provided 'prolonged' pain relief because the boy progressively recovered from back pain over 9 month therapy and is now fully ambulant." Office Action, p. 7. Applicant respectfully traverses this rejection.

According to the Examiner, Geusens discloses "prolonged pain relief" because the patient described in Geusens received a total of 300 mg of pamidronate via intermittent IV infusions over nine months and progressively recovered from his back pain. Claim 1 has been amended to recite that the chronic spinal mechanical pain is relieved for at least three months *following the most recent administration* of the bisphosphonate. This amendment is supported by the specification, which describes a study of pamidronate administration to three patients suffering from daily chronic spinal mechanical pain. Specification, p. 8-9. All three patients were pain free *six months* after their last dose of pamidronate. *Id.* Geusens does not disclose, suggest, or render predictable the claimed duration of pain relief following the most recent dose of a bisphosphonate.

As previously argued, Geusens does not teach that a bisphosphonate has any effect on pain relief. Even if Geusens did include such a teaching, however, there is no teaching that a bisphosphonate would have the claimed prolonged post-administration effect on pain relief. Geusens discloses that the patient received 300 mg of pamidronate by intermittent infusion over nine months. Geusens does not disclose that the pamidronate therapy was stopped after nine months. In fact, pamidronate had been given for at least one year. Geusens, p. 390, 2nd para. ("after 1 yr of treatment with pamidronate"). Further, pamidronate therapy was on-going - Geusens states: "How long should bisphosphonates be given? We plan to stop bisphosphonate treatment when no further increase in bone density can be detected during follow-up every 6 mo." *Id.* at 393, last para. Thus, Geusens does not disclose, suggest, or render predictable chronic spinal mechanical pain relief for at least three months following the most recent dose of a bisphosphonate. Geusens would not lead one of ordinary skill in the art to recognize any association between a bisphosphonate and

chronic spinal mechanical pain relief, much less the claimed duration of relief following the last dose of the bisphosphonate.

Accordingly, for the reasons stated above, this rejection should be withdrawn.

Conclusion

In view of the above remarks, it is respectfully requested that the pending claims be allowed and the case passed to issue.

If there are any other issues remaining, which the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

Dated: July 28, 2009

Respectfully submitted,

By _____

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